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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,818	12/06/2001	Kevin P. Baker	GNE.2630PIC4	1321

7590 03/19/2004

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,818	BAKER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-27 and adding new claims 28-33, filed on 06 December 2001 is acknowledged.

Thus claims 28-33 are pending and under consideration.

2. **Priority:**

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no. 09/946,374 filed on 04 September 2001, because, although the polypeptide of SEQ ID NO:77 (PRO1293) and the nucleic acid encoding said PRO1293 polypeptide, as well as an antibody that binds to said polypeptide are disclosed in application 09/964,374, none of the parent applications provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims 27-33, is afforded an effective filing date of 06 December 2001, which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 12/06/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 12/06/01.

Information Disclosure Statement:

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3a. Neither of the references, cited on the PTO-1449 forms submitted by Applicants on 11/08/02 and 09/03/02 have been considered, because the copies of these references cannot be located. Kindly, submit the copies of these references with your response to this office action, so that they can be considered.

Specification:

4a. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections under 35 U.S.C. §101/112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 28-33 are rejected under 35 U.S.C. §101, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 28-33 of the instant invention are directed to a an antibody that binds to the polypeptide of SEQ ID NO:77. The specification designates the polypeptide of SEQ ID NO:77, as "PRO1293", and describes it as having homology to an immunoglobulin heavy chain variable region protein, (page 79, lines 36-40). The PRO1293 polypeptide is described as having a signal sequence, N-glycosylation site, transmembrane domain, cell attachment sequence and Coproporphyrinogen 111 oxidase proteins, (see figure

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46). However, besides these structural characterizations, the specification does not disclose any information regarding physiologic activity or functional characteristics of the PRO1293 polypeptide.

The specification asserts that the PRO1293 gene encoding the PRO1293 polypeptide is amplified in the genome of certain human lung, colon and/or breast cancers and/or cell lines, (Example 143, on page 494 line 20, and table 8 on page 503). Applicants assert that gene amplification is associated with over-expression of the gene product, indicating that the polypeptides are useful targets for therapeutic intervention in certain cancers such as colon, lung and breast and other cancers, (page 494, lines 20-25). However, instant specification does not demonstrate that the PRO1293 polypeptide is actually overly expressed in any of the cancers mentioned. Applicants have not shown that there is a relationship between protein expression and the over-expression of the gene.

Therefore, since the instant specification provides no information regarding the physiological significance, functional characteristics or any conditions that involve the polypeptide of SEQ ID NO:77, (PRO1293 polypeptide), the PRO1293 polypeptide, lacks specific and substantial asserted utility or a well established utility. As a result, antibodies that bind to the PRO1293, also lack specific asserted utility or a well established utility.

3b. Claims 28-33 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in

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the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the PRO1293 polypeptide. Although the specification describes the structure of PRO1293 polypeptide, and one of ordinary skill in the art can make antibodies against it, the skilled artisan would not know how to use said PRO1293 polypeptide or antibodies against it, because Applicants do not provide any information regarding biological activity or physiological characterization of said polypeptide.

Claim rejections-35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4a. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "specifically" recited in instant claim 33 is a relative term which renders the claims indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. §102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 27-33 are rejected under U.S.C. § 102 (a) as being anticipated by Botstein et al (WO2000053751; published 14 September 2000).

Botstein et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:77 of the instant application. (See attached copies of the comparison of SEQ ID NO:77 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Botstein et al also disclose an antibody that binds to said polypeptide, (page 54, line 10). Botstein et al disclose an antibody fragment, (page 58, lines 19-35), a monoclonal antibody (page 59, lines 6-19) and a humanized antibody (page 59, lines 27-35).

Instant claims 28-33 are drawn to an antibody (monoclonal, fragment, humanized or labeled) that binds to the polypeptide of SEQ ID NO:77. Therefore, the Botstein et al reference meets all the limitations recited in claims 28-33, because the antibody disclosed in this reference would be expected to bind completely to the polypeptide of SEQ ID NO:77 of the instant application. Therefore, the Botstein et al reference anticipates the instant claims 28-33 in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-

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0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
15 March 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600